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Filed : December 14, 2001

REMARKS

Claims 6-12 have been withdrawn as being directed towards a non-elected species. Claim 1 has been amended, and new Claims 13-20 have been added. Accordingly, Claims 1-5 and 13-20 are presented for examination. No new matter has been added by this amendment.

Discussion of Rejection Under 35 USC §103(a)

The Examiner rejected Claims 1-5 under 35 USC §103(a) as being unpatentable over Virtanen in view of Barany, et al. or Kozwich, et al. The Examiner argued that it would have been obvious to one skilled in the art that the Virtanen optical disc could incorporate the amplification agent and detection agent as disclosed in Barany, et al. or Kozwich, et al. Applicant respectfully disagrees.

The initial burden is on the Examiner to demonstrate that the claimed invention was *prima facie* obvious. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references taken together must suggest all the claim limitations. The suggestion to make the claimed combination, and the reasonable expectation of success, must be found in the prior art, and not based on Applicant's own disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner fails to meet his burden of establishing a *prima facie* case of obviousness. First, the Examiner has not pointed to any suggestion or motivation, either in the references themselves or the knowledge generally available in the art to combine the teachings of Virtanen with either Barany, et al. or Kozwich, et al. Virtanen does not provide any motivation to carry out the claimed amplification assays. Barany, et al and Kozwich, et al do not provide any motivation to include their amplification assays within a bio-disc based system, such as that described by Virtanen.

The Examiner has not explained how there would be a reasonable expectation of success upon making either combination. One of ordinary skill in the art would not expect that the nitrocellulose sandwich assay described in Example 5 of Kozwich would be useful within a centrifugal bio-disk system as recited in the pending claims. Also, one of ordinary skill in the art

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would not believe that the reactions performed on the static addressable array recited by Barany, et al. in Example 1, would be successful within a centrifugal bio-disk system as recited in the pending claims.

Finally, the Examiner has not explained how the combination of references teaches or suggests all the claim limitations. None of the references appear to teach an analyte detector unit, with all the claimed features of a primary detector that selectively reacts with the analyte. Similarly, none of the references appear to teach an amplification unit fluidly connected to the analyte detector unit and comprising a plurality of secondary detection agents, wherein an amplification agent can change a plurality of detection agents from a negative to a positive detection state. Referring to Claim 3, there does not appear to be a teaching in any reference of a device with primary detector and/or secondary detection agents that are bound to the optical disc. Nor has the Examiner explained which reference teaches that an amplification agent can comprise an enzyme which is released from the primary detector, as recited in Claim 4.

The remarks made by the Examiner in the Office Action do not support a *prima facie* case of obviousness, as they fail to meet any element of the required standard as described above. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 USC § 103(a).

The Examiner has also not made the required factual inquiries outlined in *Graham v. John Deer Co.* in order to establish a proper *prima facie* case of obviousness. For example, the Examiner has not described the difference or differences between each claim and the applied references. Nor has the Examiner described the proposed modification of the applied references necessary to arrive at the claimed subject matter. Additionally, the Examiner has not explained why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification. For this reason, the Examiner has failed to meet his burden of demonstrating that the combination of references makes the invention, as a whole, obvious to one of ordinary skill in the art.

In addition, even if the Examiner had met his burden, the combination of references is insufficient to support the allegation of non-obviousness. For example, the cited section of Virtanen teaches a system for detecting particular DNA in a mixture by first hybridizing a target DNA to a probe that includes a thiol group at one end. An isothiocyanate coated electrode is then used to immobilize the thiolated probe/target DNA complex. The non-hybridized DNA is then washed away, leaving only immobilized target DNA. The target DNA molecules that are hybridized to the immobilized probes are then released by heating of the optical disc. The newly

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released target DNA molecules are then flushed into an assay area, followed by DNA ligase. If the proper target DNA sequence has moved into the assay area, the ligase connects two side arm molecules, which results in a positive read of the optical disc assay.

However, unlike Claim 1, there is no mention in Virtanen of an amplification agent that is capable of changing a plurality of detection agents between a negative and positive detection state. The target DNA that is flushed into the assay area is only designed to act on a single set of side arm molecules. Thus, the advantageous amplification effect recited in the pending claims is not found within Virtanen.

This deficiency is not overcome by either Kozwicz, et al. or Barany, et al. Kozwicz, et al. only describe the use of a nitrocellulose membrane which is sandwiched with a second membrane so that, in the presence of the appropriate target, a visible line appears on the sandwiched membrane device. There is no suggestion to incorporate the amplification reagents of Example 5 into an optical disc. There is also no teaching that such incorporation would work for the intended purpose of creating an amplification detection system as recited in the pending claims.

Similarly, Barany, et al. describe a polymerase chain reaction (PCR) process that occurs on an addressable array, and not within any type of optical disc. Moreover, there is no description of using such a system within an optical disc. Accordingly, there is no expectation that such an assay would work within a centrifugal bio-disc system such as recited in the claims.

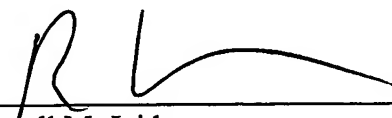
For all of the above reasons, Applicant respectfully requests withdrawal of the rejections under 35 USC § 103(a) and allowance of the pending claims.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 10/15/04

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